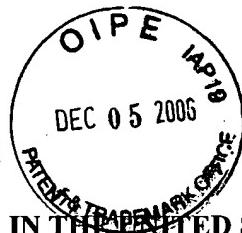


TOYA108.010APC



TM

Receipt

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Hatake, et al.  
Appl. No. : 10/564,302  
Filed : January 10, 2006  
For : DRUG FOR CANCER THERAPY  
Examiner : Unknown

Group Art Unit 2817

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

November 30, 2006

  
(Date)  
Che Swyden Chereskin, Ph.D., Reg. No. 41,466

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents  
P.O. Box 1450  
Office of Initial Patent Examination  
Customer Service Center  
Alexandria, VA 22313-1450

Dear Sir:

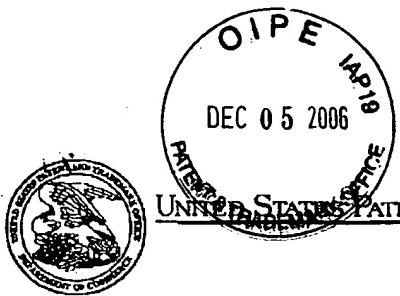
Applicants hereby request that the Official Filing Receipt, a copy of which is enclosed, be corrected to reflect the amended title of the invention. Presently, the Filing Receipt incorrectly shows the title as Medicine for Cancer Therapy. The title should be DRUG FOR CANCER THERAPY. Supporting documentation is provided herewith.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Nov. 30, 2006

By: Che S. Chereskin  
Che Swyden Chereskin, Ph.D.  
Registration No. 41,466  
Agent of Record  
Customer No. 20,995  
(949) 760-0404



UNITED STATES DEPARTMENT OF COMMERCE  
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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/564,302	01/10/2006	2817	2400	TOYA108.010APC	1	26	9

## CONFIRMATION NO. 7332

20995  
KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

## FILING RECEIPT



\*OC000000019092072\*

Date Mailed: 06/06/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Kiyohiko Hatake, Tokyo, JAPAN;  
Yasuhito Terui, Tokyo, JAPAN;  
Yuji Mishima, Tokyo, JAPAN;  
Akio Yamada, Kanagawa, JAPAN;  
Takuma Sakurai, Kanagawa, JAPAN;  
Takehito Itoh, Kanagawa, JAPAN;

**Power of Attorney:** The patent practitioners associated with Customer Number 20995.

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/JP05/04123 03/09/2005

## Foreign Applications

JAPAN 2004-080454 03/19/2004

If Required, Foreign Filing License Granted: 06/02/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/564,302**

Projected Publication Date: 09/14/2006

Non-Publication Request: No

**Early Publication Request: No**

**Title**

**DRUG**

-Medicine for cancer therapy

**Preliminary Class**

330

## **PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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### **LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15**

#### **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted

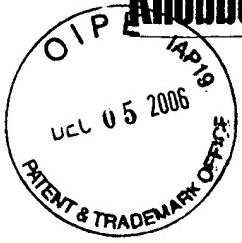
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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



# Knobbe Martens Olson & Bear LLP

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## CERTIFICATE OF MAILING BY "EXPRESS MAIL"

**Attorney Docket No.** : TOYA108.010APC  
**Applicant(s)** : Hitake, et al.  
**For** : DRUG FOR CANCER THERAPY  
**Attorney** : Che Swyden Chereskin, Ph.D.  
**"Express Mail"**  
**Mailing Label No.** : EV 718233910 US  
**Date of Deposit** : January 10, 2006

EV718233910US

I hereby certify that the accompanying

Transmittal; Application in 51 Preliminary Amendment in 7 pages; Declaration and Power of Attorney in 3 pages; Assignment; Recordation Form Cover Sheet in 3 pages total; First page of international application as published; Paper sequence listing in 3 pages and CRF diskettes in duplicate; International Search Report; One sheet of drawing; Forms PCT/IB/304 and PCT/IB/308; Check for Filing Fee; Return Prepaid Postcard

are being deposited with the United States Postal Service "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above and are addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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011006

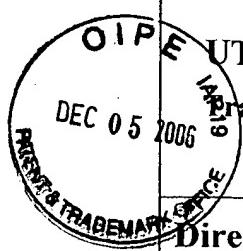
San Diego  
619-235-8550

San Francisco  
415-954-4114

Los Angeles  
310-551-3450

Riverside  
951-781-9231

San Luis Obispo  
805-547-5580



**NATIONAL PHASE  
UTILITY APPLICATION**  
Transmittal to the (DO/EO/US)  
Under 35 USC 371

Attorney Docket No.: TOYA108.010APC  
First Named Inventor: Kiyohiko Hatake  
Int'l Application No.: PCT/JP2005/004123  
Int'l Filing Date: March 9, 2005  
Priority Date Claimed: March 19, 2004  
Title: DRUG FOR CANCER THERAPY  
Express Mail Label No.: EV 718233910 US

**Direct all correspondence to Customer No.: 20995**

Date: January 10, 2006

Page 1 of 2

**Mail Stop PCT**  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria VA 22313-1450

The following enclosures are transmitted herewith to be filed in the patent application of:

Inventors:

- |                    |                   |
|--------------------|-------------------|
| 1. Kiyohiko Hatake | 2. Yasuhito Terui |
| 3. Yuji Mishima    | 4. Akio Yamada    |
| 5. Takuma Sakurai  | 6. Takehito Itoh  |

**APPLICATION ELEMENTS:**

- (X) This is a FIRST submission of items concerning a filing under 35 U.S.C. § 371.
- (X) This is an Express Request to begin national examination procedures (35 U.S.C. § 371(f)).
- (X) A copy of the International Application as filed (35 U.S.C. § 371(c)(2)) has been communicated by the International Bureau. A copy of PCT/IB/308 is enclosed.
- (X) Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. § 371(c)(3)) have not been and will not be made.
- (X) Application in 51 pages.
- (X) An Oath or Declaration signed by the inventors (35 U.S.C. § 371(c)(4)).

**OTHER APPLICATION PARTS:**

- (X) Preliminary Amendment in 7 pages.
- (X) Sequence Listing on paper in 3 pages and on CRF diskette in duplicate.
- (X) Recordation form cover sheet and Assignment in 3 total pages (cover sheet & assignment).
- (X) First page of international application as published
- (X) International Search Report.
- (X) One sheet of drawing
- (X) Form PCT/IB/304.
- (X) Return prepaid postcard.

**NATIONAL PHASE  
UTILITY APPLICATION**  
**Transmittal to the (DO/EO/US)  
Under 35 USC 371**

Attorney Docket No.: TOYA108.010APC  
First Named Inventor: Kiyohiko Hatake  
Int'l Application No.: PCT/JP2005/004123  
Int'l Filing Date: March 9, 2005  
Priority Date Claimed: March 19, 2004  
Title: DRUG FOR CANCER THERAPY  
Express Mail Label No.: EV 718233910 US

**Direct all correspondence to Customer No.: 20995**

Date: January 10, 2006

Page 2 of 2

**FILING FEES:**

FEE CALCULATION				
FEE TYPE & DETERMINATION		LARGE FEE	CALCULATION	TOTAL
Basic Filing Fee under 1.492(a)		1631 (\$300)		\$300
Search Fee under 1.492(b) ( <i>enter one in TOTAL column</i> )				
(1) USPTO was ISA/IPEA & claims satisfy Art. 33 (1)-(4)		1640 (\$0)		
(2) USPTO was the ISA (noncompliant claims)		1641 (\$100)		\$400
(3) Foreign Search Report Enclosed		1642 (\$400)		
(4) No Search Report Enclosed		1632 (\$500)		
Examination Fee under 1.492(c) ( <i>enter one in TOTAL column</i> )				
(1) USPTO was ISA/IPEA & claims satisfy Art. 33 (1)-(4)		1643 (\$0)		\$200
(2) Non US IPEA or Noncompliant Claims		1633 (\$200)		
Excess Claims	26 - 20 = 6	1615 (\$50)	6 x 50 =	\$300
Excess Ind. Claims	9 - 3 = 6	1614 (\$200)	6 x 200 =	\$1,200
Assignment		8021 (\$40)	* x 40 =	\$40
<b>TOTAL FEE PAID (If Different Than Fee Due)</b>				<b>\$2,440</b>

A check in the amount of \$2,440 to cover the Total Fee Due is enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required, now or in the future, or credit any overpayment to Account No. 11-1410.

Che S. Chereskin

Che Swyden Chereskin, Ph.D.  
Registration No. 41,466  
Agent of Record  
Customer No. 20,995  
(949) 760-0404

2277724  
011006

## DESCRIPTION

## Drug for Cancer Therapy

## Field of the Invention

The present invention relates to a drug containing a lactoferrin hydrolysate mixture, a partial peptide of lactoferrin that can be isolated from the lactoferrin hydrolysate mixture or a partial peptide of lactoferrin that can be prepared by chemical synthesis or the like, which have an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer, as an active ingredient. More precisely, the present invention relates to a drug having an action of enhancing sensibility to an antibody drug of cancer cells having resistance to the antibody drug.

## Related Art

The mechanism for antibodies to recognize a specific antigen and eliminate foreign substances out of organisms have long been studied. Immunoglobulin preparations are well known as application of antibodies to therapeutic treatments. However, they have problems such as insufficient titer and contamination of unknown infection sources.

The invention of the monoclonal antibody preparation technique by Milstein and Kohler brought breakthroughs in various antibody techniques. Today, in the so-called post-genome era, specific genes of tumor cells and pathogenic factors and expression products thereof are being successively elucidated. The antibody techniques are greatly contributing to development of research methods targeting them and therapeutic methods by utilizing them.



TOYA108.010APC

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	:	Hatake, et al.
Int'l Appl. No.	:	PCT/JP2005/004123
Int'l filing date	:	March 9, 2005
For	:	DRUG FOR CANCER THERAPY (AMENDED)
Examiner	:	unknown
Group Art Unit	:	unknown

**PRELIMINARY AMENDMENT AND**  
**VERIFICATION UNDER 37 C.F.R. § 1.821 (f)**

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Preliminary to examination on the merits, please amend the above-captioned U.S. application as follows.

**Amendments to the Specification** begin on page 2 of this paper.

**Amendments to the Claims** are reflected in the listing of claims which begins on page 3 of this paper.

**Remarks/Arguments** begin on page 7 of this paper.

Int'l Appl. No. : PCT/JP2005/004123  
Int'l filing date : March 9, 2005

#### AMENDMENTS TO THE SPECIFICATION

*Please change the title as follows:*

MEDICINE DRUG FOR CANCER THERAPY

*On page 1 of the Specification, after the Title and before the Field of the Invention statement starting on line 1, please insert the following section:*

#### Related Applications

This application is the U.S. National Phase under 35 U.S.C. § 371 of International Application PCT/JP2005/004123, filed March 9, 2005, which was published in a language other than English, which claims priority of JP 2004-080454, filed March 19, 2004.

*On page 41 before Claim 1, please amend as follows:*

WHAT IS CLAIMED IS: CLAIMS

Int'l Appl. No. : PCT/JP2005/004123  
Int'l filing date : March 9, 2005

### REMARKS

Claims 1, 3-8, 10-14, 16-20, and 22-26 have been amended to conform with the rules of practice before the U.S. Patent and Trademark Office. The specification has been amended to recite the International Application and priority application. Claims 1-26 are presented for examination. No new matter is added by this amendment.

Enclosed herewith are: (1) a paper copy of the Sequence Listing, and (2) a computer readable version of the Sequence Listing (2).

### VERIFICATION UNDER 37 C.F.R. § 1.821 (f)

All of the sequences in the attached Sequence Listing are included in the application as filed. As required under 37 C.F.R. § 1.821 (f), I hereby verify that the data on the enclosed disks and the paper copies of the Sequence Listing are identical.

### **Conclusion**

Should there be any questions concerning this application, the Examiner is invited to contact the undersigned agent at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Jan. 10, 2006

By: Che S. Chereskin  
Che Swyden Chereskin, Ph.D.  
Registration No. 41,466  
Agent of Record  
Customer No. 20,995  
(949) 760-0404

2274193  
010906